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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : David M. Stern, et al.  
U.S. Serial No.: 09/638,648 Examiner: T.N. Ton  
Filed : August 14, 2000 Art Unit: 09/638,648  
For : A METHOD TO INCREASE CEREBRAL BLOOD FLOW IN  
AMYLOID ANGIOPATHY

1185 Avenue of the Americas  
New York, New York 10036  
April 30, 2001

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

COMMUNICATION IN REPLY TO MARCH 30, 2001 OFFICE ACTION

This Communication is submitted in reply to the March 30, 2001 Office Action which was issued by the U.S. Patent and Trademark Office in connection with the above-identified application. A reply to the March 30, 2001 Office Action is due April 30, 2001. Therefore, this Communication is being timely filed.

Species Election Requirement

The Examiner alleged that this application contains claims directed to the following patentably distinct species of the claimed invention:

- 1) Subject to which the method will be administered:
  - a) Transgenic non-human animal

b) Human subject

The Examiner took the position that these species are patentably distinct from each other. For example, the Examiner stated that providing a transgenic animal requires the steps of selecting a suitable non-human animal, a suitable transgene and the steps of expressing the transgene to obtain a suitable phenotype. The Examiner stated that these methods are not required to reduce to practice the method of decreasing cerebral vasoconstriction in a human subject by administering an inhibitor for RAGE.

2) Inhibitors of receptor for advanced glycation endproduct (RAGE):

- a) An inorganic molecule
- b) A polypeptide
- c) A nucleic acid molecule
- d) Soluble RAGE
- e) An antibody which specifically binds to RAGE

The Examiner took the position that these species are patentably distinct species from each other, as each inhibitor requires has different structural and mechanistic properties, different modes of action, and further, a reference for one species would not necessarily anticipate or even make obvious another species. The Examiner stated that applicants are required under 35 U.S.C. §121 to elect a single disclosed species, even though this requirement is traversed.

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The Examiner stated that applicants are required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner stated that currently, claims 1, 12 and 16, directed to a method of administering to a subject an inhibitor of RAGE, are generic.

The Examiner stated that applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. The Examiner stated that an argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The Examiner stated that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141. The Examiner stated that if claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

The Examiner stated that should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that

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this is the case. In either instance, the Examiner stated that if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In reply, applicants elect the following:

- 1) Subject to which the method will be administered: a) transgenic non-human animal.
- 2) Inhibitors of receptor for advanced glycation endproduct (RAGE):  
d) soluble RAGE.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone at the number provided below.

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No fee is deemed necessary in connection with the filing of this Communication. If any additional fees are required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:  
Assistant Commissioner for Patents  
Washington, D.C. 20231

*Jane M. Love* 4/30/01  
Date

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